USA, Plaintiff,

v.

ELIZABETH A. HOLMES and RAMESH "SUNNY" BALWANI, Defendants

Case No. 5:18-cr-00258-EJD-1
United States District Court, N.D. California
Nov 05, 2019

Davila, Edward J., United States District Court Judge

ORDER GRANTING MOTION TO COMPEL Re: Dkt. No. 67

*1 Defendant Holmes moved, on April 15, 2019, to compel federal prosecutors (the "Prosecution") to produce material responsive to six requests from FDA and CMS (the "Agencies"). Dkt. No. 67. Those requests are:

Category 1: Any and all correspondence or communications regarding Theranos between the government and John Carreyrou, The Wall Street Journal, or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same.

Category 2: Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos.

Category 3: Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or interagency correspondence) regarding same.

Category 4: Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology.

Category 5: Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same.

Category 6: Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.

Id. at 1-2. Defendant Balwani joined the motion. Dkt. No. 68. The court then held a series of hearings and issued multiple interim orders. See, e.g., Dkt. Nos. 84, 111, 115, 134. This order assumes familiarity with the briefing for those hearings, the discussions at those hearings, and the interim orders. The key facts here are that the Agencies represented that they intended to produce responsive documents (Dkt. Nos. 79-4, 79-5), that the court directed the agencies to search for and produce all documents responsive to those requests by October 2, 2019 (Dkt. No. 111), that Defendants have raised issues concerning the Agencies' productions (Dkt. Nos. 121, 170), that, as of the November 4, 2019 hearing, the Agencies had not completed their productions (Dkt. No. 170), and that the court has not yet issued an order—under Federal Rule of Criminal Procedure 16—compelling the Prosecution to ensure responsive documents are produced. The court will now grant the motion.

*2 Rule 16 "grants criminal defendants a broad right to discovery." United States v. Stever, 603 F.3d 747, 752

(9th Cir. 2010). The government must disclose documents within its "possession, custody, or control" that are "material to preparing the defense." Fed. R. Crim. P. 16(a)(1)(E)(i). Under Ninth Circuit case law, prosecutors have possession of discoverable material where they have knowledge of and access to the documents, even if those documents are physically held by other government agencies. United States v. Santiago, 46 F.3d 885, 893-94 (9th Cir. 1995). An agency's participation in an investigation is sufficient, but not necessary, to establish that prosecutors have access to the agency's information. Id. at 893; see also United States v. W. R. Grace, 401 F. Supp. 2d 1069, 1078 (D. Mont. 2005) ("The prosecution is in possession of information held by any government agency provided the prosecution has knowledge of and access to the information. This is so regardless of whether the agency holding the information participated in the investigation." (citation omitted)).

The Prosecution does not oppose Defendants obtaining the sought-after documents, but it argues that it cannot be compelled to produce the documents under Rule 16 because it lacks access. See, e.g., Dkt. No. 170 at 1-2. The court disagrees. Even though the Agencies are not part of DOJ, the Prosecution's involvement with the Agencies' discovery efforts reveals a relationship that includes significant access, communication and assistance, such as CMS's use of DOJ's Litigation Technology Service Center. This cooperative relationship moves the Prosecution closer to privity of knowledge and control of the information sought. The Prosecution's access to the requested documents is further shown through its dealings with the Agencies prior to the filing of this motion. The Prosecution requested both "non-public" "[r]ecords and files maintained or created by the [FDA] concerning Theranos," and interviews with FDA employees about their interactions with Theranos. Dkt. No. 67-8. FDA granted these requests. Dkt. No. 67-9. The Prosecution has already produced a significant number of FDA and CMS documents that it may offer at trial. And, the Prosecution issued litigation hold notices for this case to the Agencies. Dkt. No. 67-10. The Prosecution directed the Agencies, "You must take affirmative steps to ensure that all employees subject to the litigation hold understand and comply with the litigation hold, and provide employees further instruction, direction, and oversight." Id. at 3 (citation omitted). The court finds that the Prosecution has knowledge of and access to the at-issue documents. The court orders the Prosecution to produce the documents discussed below as part of their Rule 16 obligation, and to assist the Agencies however possible to ensure the timely production of documents.

The court now turns to the alleged deficiencies in the Agencies' productions. First, Defendants have raised concerns as to the Agencies' preservation efforts. As to FDA, Defendants contend that over 1000 emails from a single witness have been produced as fragmentary documents—i.e, that the produced emails omit portions of the original email, such as the "to," or "from," or the body fields. They contend that this fragmentation could indicate that the emails have been deleted and subsequently restored. FDA represented to the court that it has no reason to believe that the emails were destroyed, but rather that its initial investigation suggests that the emails were somehow corrupted. Defendants also contend that CMS and FDA have failed to produce some hardcopy documents. CMS stated that it is "following up" on this issue. Dkt. No. 170 at 4-5. The court orders that the Agencies shall continue their investigations of these issues and shall disclose the procedures and results of their investigations to the parties no later than November 26, 2019.

*3 Defendants complain that FDA failed to run certain search terms that they contend are responsive to the six requests. The court orders that FDA shall run searches of all of its custodians' documents using the following terms: "LDT", "Laboratory Developed Test", "Theranos", "fingerstick" or "finger stick", and "nanotainer". FDA shall produce any responsive documents returned by these searches.

Defendants point out that the court initially ordered the Agencies to complete their document productions by October 2, 2019 and extended the deadline to October 25, 2019, but neither agency has completed their production. The court orders the Agencies and the Prosecution to complete the production of documents by December 31, 2019.

Finally, the court orders the Agencies, the Prosecution, and Defendants to meet and confer on the above issues, and other discovery related matters. The topics of their conference(s) shall include, but are not limited to, the following: (a) whether the Agencies have or will produce employee text messages, (b) any deficiencies in FDA's production that are attributable to FDA's instruction to employees to manually search for responsive documents instead of forensically searching for, collecting, and reviewing documents, (c) the terms the

Agencies use to search for and collect potentially responsive documents, and (d) FDA's redactions to documents and withholding of duplicate documents.

A further status conference is set for 10:00 a.m. on January 13, 2020. All parties shall file a joint status report no later than January 9, 2020.

IT IS SO ORDERED.

Dated: November 5, 2019

EDWARD J. DAVILA

United States District Judge

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